



Design and Analysis of Non-Inferiority Trials (Chapman & Hall/CRC Biostatistics Series)

Mark D. Rothmann, Brian L. Wiens, Ivan S.F. Chan

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The increased use of non-inferiority analysis has been accompanied by a proliferation of research on the design and analysis of non-inferiority studies. Using examples from real clinical trials, **Design and Analysis of Non-Inferiority Trials** brings together this body of research and confronts the issues involved in the design of a non-inferiority trial. Each chapter begins with a non-technical introduction, making the text easily understood by those without prior knowledge of this type of trial.

Topics covered include:

- A variety of issues of non-inferiority trials, including multiple comparisons, missing data, analysis population, the use of safety margins, the internal consistency of non-inferiority inference, the use of surrogate endpoints, trial monitoring, and equivalence trials
- Specific issues and analysis methods when the data are binary, continuous, and time-to-event
- The history of non-inferiority trials and the design and conduct considerations for a non-inferiority trial
- The strength of evidence of an efficacy finding and how to evaluate the effect size of an active control therapy

A comprehensive discussion on the purpose and issues involved with non-inferiority trials, **Design and Analysis of Non-inferiority Trials** will assist current and future scientists and statisticians on the optimal design of non-inferiority trials and in assessing the quality of non-inferiority comparisons done in practice.

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